

REMARKS

The application is believed to be in condition for allowance.

Claim Rejections - Obviousness-type Double Patenting

The Official Action provisionally rejected claims 1, 3-4, 7-8, 13, 23-28, and 35-36 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 and 17 of co-pending Application No. 12/067817.

In response, the provisional rejection is noted. However, since this rejection has been indicated as provisional, Applicants respectfully submit that no Terminal Disclaimer is required at this time. Should co-pending U.S. Application 12/067,817 go to allowance, for example, the matter of the provisional rejection with respect to the present application should be re-visited and a determination made at that time in consideration of any amendments made to the claims of the present and the co-pending applications.

Claim Rejections - Section 112, first paragraph

The Official Action rejected claims 1, 3, 4, 7, 8, 13, 23-28, 35 and 36 under 35 USC 112, first paragraph as failing to comply with the written description requirement. The Official Action contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventors at the time the application was filed, had possession of the claimed invention.

The Official Action contends that the recitations of "water between 32% to 35% by weight" in claim 1 and "water at between 13.9% and 43.1% by weight" in claim 23 do not appear to be supported in the specification or claims as originally filed.

Applicants respectfully disagree. The specification originally filed discloses a plurality of examples which, taken as a whole, support the water as recited in the claims.

As to claim 1, the lower bound of water content as a percentage of weight is disclosed at Example 5 (Agar), wherein water content is disclosed at 32.1 % at page 19, line 23.

The upper bound is derived from Example 8 (Agar). In the table of components on page 24, the specification discloses hot water at "about" 12% within a list of ingredients that adds up to a total of only 77.55%. Hence some 22.45% of the composition by weight is not listed.

The remaining 22.45% is disclosed in the description that follows the table on page 25 of the specification. Specifically, at line 5, the third step of the process, additional water is disclosed. In step 3, the hydroxides are prepared from a cold aqueous solution and added to the mixture. This cold water introduced with the potassium hydroxide (7.7%) and the sodium hydroxide (1.1%) that is

otherwise not listed in the table on page 25 (that is, page 25 only lists hot water) is the one remaining ingredient disclosed in the Example, and therefore makes up the remaining 22.45% not accounted for in the table. Accordingly, the upper bound of claim 1 is 12% (hot water) plus 22.45% (cold water) and thus 34.45% water or (rounded up) 35% as recited in the claim.

Again, the weights given in the table on page 24 are dry weights. It is respectfully submitted that it is common practice in the field to convert solid hydroxides into a solution before mixing, as disclosed in the steps on page 25. Thus, the 8.8% weight hydroxides are mixed with 22.45% weight water to make a strong (about 28% concentration) aqueous solution of potassium and sodium hydroxide that together comprise 31.25% of the components of Example 8, by weight.

This is further apparent to the skilled person from the disclosure of Example 8 as i) no other substance is disclosed in the Example (e.g., all components are accounted for in the page 24 table except for the cold water of the hydroxides), and ii) all the other tables provided in the Examples of the specification add up to 100%, so it would be apparent to the skilled person that there is a missing line in the list of components in Example 8, thereby drawing the skilled person's attention to any component(s) in the description that follows that would account for the missing

weight; the only logical conclusion is the missing 22.45% is the cold water of the hydroxide step.

This missing line was provided as an amendment to the specification in the response filed on June 2, 2011.

Further, the skilled person would have recognized a need for an amount of water for dissolving the hydroxides. Hydroxides are very soluble in water, but the alternative of their addition in the conventionally supplied form of solid flakes to a hot gel solution may adversely affect at least adjacent regions of the gel. "Cold" water specified in step three of page 25 refers to removing the significant exothermic heat generated at the time of solution of the hydroxides.

Accordingly, it is respectfully submitted that the recitation of water between 32% to 35% by weight in claim 1 is supported in the specification as originally filed in compliance with the written description of Section 112, first paragraph.

As to claim 23, a water content of 13.90% is disclosed in Example 6. The listed ingredients add up to 86.1%, with a total indicated as 100%. Therefore, the water component indicated as "q.s." must be the difference between 100% and 86.1%, or 13.90% as recited. Similarly, Example 7 discloses water as the difference between the other ingredients 56.91% and the total 100%: therefore, water content "q.s." is 43.09% or rounded 43.1% as recited.

Therefore, it is respectfully submitted that support for the claimed recitation of a gelling agent comprising water at between 13.9% and 43.1% by weight is also disclosed in the specification as originally filed, and is therefore proper in view of the written description requirement of Section 112.

Withdrawal of the rejections of claims 1 and 23 over the written description requirement of Section 112 is therefore respectfully submitted.

Claim Rejections - Section 103

The Official Action rejected claims 1, 3-4, 7-8, 13, 23-25, 27-28 and 35-36 under 35 USC 103(a) as being unpatentable over Bolton et al. (US 4,814,179; "BOLTON") as evidenced by Athanikar (US 6,379,651; "ATHANIKAR").

The Official Action rejected claim 26 under 35 USC 103(a) as being unpatentable over BOLTON and ATHANIKAR, and further in view of Huang et al. (US 6,485,738; "HUANG").

The rejections are respectfully traversed.

In rejecting the claims, the Official Action identifies the drying process of BOLTON in order to satisfy the recitation of water content in the semi-solids recited by claims 1 and 23. The Official Action concedes that the end product of BOLTON has a water content of only 4.6%, and therefore does not teach a product having the composition recited in the claims. Instead, however, the Official Action offers the wet slurry from which the dry product of BOLTON is

derived, alleging that "it is reasonable to conclude that during the drying process that amount of water would be in the range" recited in the claims "because the water content goes from 45% before drying to 4.6% after drying."

However, even if the process disclosed by BOLTON should inadvertently lead, however temporarily, to a water content as recited in the independent claims, BOLTON makes no teaching or suggestion toward a semi-solid product having the recited features. That is, BOLTON makes absolutely no teaching or suggestion to the skilled person that of any semi-solid gel bead or semi-solid composition for use in single-dose form in personal oral, dental, or skin care having the recited composition because, taken most favorably, BOLTON at best only teaches a slurry having this composition.

Further, BOLTON fails to teach this composition with sufficient specificity that the skilled person could reasonably have understood the claimed invention as obvious. For example, the Official Action concedes that it cannot identify when the target composition appears in BOLTON's drying process, just as it cannot identify when it is passed by as the drying process continues. Thus, any alleged teaching toward the invention claimed is so non-specific that no reasonable conclusion can be made that the claimed product was known in the skill of the art.

Further, BOLTON expressly teaches not to prepare a composition as recited, but instead explicitly teaches to dry the mixture to a water content of only 4.6%. Therefore, BOLTON explicitly teaches away from the semi-solid composition claimed in the independent claims.

Yet further, BOLTON could not have reasonably led the skilled person to the claimed semi-solid composition because BOLTON also teaches away from semi-solid compositions. That is, the product taught by BOLTON is expressly disclosed as hard and brittle, not semi-solid (see, e.g., column 4 line 66 to column 5 lines 7; see also the substantial "hardness" of BOLTON's product as described at column 7, lines 1-3).

No combination of BOLTON with secondary references ATHANIKAR and/or HUANG teaches or suggests anything that would have motivated the skilled person to modify BOLTON away from a hard, dry product.

For example, if BOLTON is best characterized in accordance with its claim 1, then BOLTON is:

[a] therapeutic composition in unit dosage form as a non-compressed tablet having a network of multitudinous air holes and passages therein and a density of less than one and capable of floating on gastric fluid in vivo and providing sustained release of the therapeutic agent over an extended period of time, comprising a matrix formed from a gelling agent containing a therapeutic agent, a therapeutically acceptable inert oil and water in the following percentages by weight based on the total weight of the tablet: gelling agent, 0.5 to 4%; oil, 10 to 20%; therapeutic agent, 50 to 75%; balance water.

To become such a product, with air holes and passages, the unit dosage must be substantially dry. Any wet slurry before drying is complete is not ready for use: e.g., it would not float. Hence, the only product taught or suggested by BOLTON is a hard, dry tablet, and there is no evidence available on the record that ATHANIKAR or HUANG suggests anything that would lead the skilled person from BOLTON's product to the semi-solid claimed.

For example, ATHANIKAR teaches a chewable preparation owing its properties to a "gum base" (e.g., column 5, line 10, but no further details are provided). ATHANIKAR does not suggest agar, nor does agar have properties like those of a chewing gum. Further, no water is disclosed in the composition.

HUANG discloses the use of mixed composition of gels, such as gelatine and agar (column 6, lines 39-30), and optionally other gelling agents as listed at column 4, lines 11-23. HUANG teaches toward a slow-release gel that carries the active ingredients to the small intestine (see column 1, lines 48-56; column 3, lines 19-37). Water content is between 1% and 20%, depending on the combination selected, but the reference does not teach to any further detail (see, for instance, column 7, line 39 (10%); column 6, line 30 (1.66%); claim 7 (1-20%)). These values of water content are far less

than the presently claimed range, and would never lead nor even suggest to the skilled person to the inventive semi-solid composition.

Thus, even when viewing the secondary references in their best possible light, there is no teaching or suggestion on the record that would have reasonably motivated the skilled person to make the inventive leap from BOLTON to the semi-solid composition claimed. Accordingly, it is respectfully submitted that obviousness is not shown.

Therefore, it is respectfully submitted that claims 1 and 23, and the claims depending respectively therefrom, are allowable over the references applied by the Official Action. Withdrawal of the rejections under Section 103 is thereby respectfully requested.

Rejoinder of the Withdrawn Claims

It is respectfully submitted that withdrawn claims 10, 11, 18, 29 and 31 each properly depend from an allowable parent claim, requiring all the recitations of the allowable parent claim. It is further respectfully submitted that withdrawn claim 31, directed to a process for making the invention as recited in claim 1, is commensurate in scope with an allowable product claim and requires all the recitations of the allowable product claim.

Accordingly, rejoinder of all the withdrawn claims is respectfully requested.

Conclusion

From the foregoing, it will be apparent that Applicants have fully responded to the August 24, 2011 Official Action and that the claims as presented are patentable. In view of this, Applicants respectfully request reconsideration of the claims, as presented, and their early passage to issue.

In order to expedite the prosecution of this case, it is requested that the Examiner telephone the attorney for Applicants at the number set forth below if the Examiner is of the opinion that further discussion of this case would be helpful.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Jeremy G. Mereness/
Jeremy G. Mereness, Reg. No. 63,422
209 Madison Street
Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

JGM/lrs